REMARKS

Claims 6-10 and 22 are pending.

New Claim 22 has been added to more particularly point out that which Applicants regard as the invention. Specifically, a plasma protein has a plurality of binding sites at which a drug may bind. The specific site at which one drug binds among the numerous binding sites in the protein may be known. For another drug that binds to the protein, however, specific sites in the protein at which that drug binds may not be known. An object of the present invention is to provide a method to determine the specific sites in the protein at which the other drug binds.

Claim 22 is supported by Examples 1 to 3 in the specification and, in particular, by Table 1 at page 27 of the specification.

Claims 6-10 have been amended to make them dependant from Claim 22 and/or to provide proper antecedent bases for the recitation of the "second or more" drugs in Claim 22.

Accordingly, no question of new matter arises and entry of the amendment is requested, respectfully.

I. Claim to Priority

At page 3 of the Office Action, the Examiner acknowledged Applicants' claim to priority. However, the Examiner did not indicate receipt of the priority document.

PAIR indicates that the priority papers were filed on April 26, 2005. Accordingly, the Examiner is requested to acknowledge receipt of the priority document.

II. Detailed Action

A. Election/Restrictions

The Examiner repeated the restriction requirement issued by telephone on May 5, 2006 and confirmed Applicants' election of Group I, without traverse.

Non-elected claims 11-17, 19 and 21, which were withdrawn from consideration, have been canceled.

B. Claim rejections - Non-Statutory Double Patenting

The elected claims were rejected on the ground of non-statutory obviousness-type double patenting as being obvious over claims 1-5 and 7-8 of U.S. Patent No. 7,029,653.

The undersigned respectfully submits that a non-statutory double patenting rejection is relevant only where the cited reference is not legally effective prior art under 35 U.S.C. § 102 or § 103. In this respect, the '653 has been cited under 35 U.S.C.§ 102(e). Accordingly, the rejection is improper and withdrawal is requested, respectfully.

C. Claim Rejections - 35 U.S.C. § 102(b) and § 102(e)

1. The elected Claims were rejected under 35 U.S.C. § 102(b) as being anticipated by *Kawai, et al.* (WO 00/78352) and *Prichard et al.*(1985).

With respect to *Kawai, et al.*, the Examiner asserted that *Kawai, et al.*teach a method of administering drugs with binding affinity for plasma protein and drugs regulating the effective dose of the drug with binding affinity for plasma protein.

The Examiner also asserted that *Kawai, et al.* teach that when the second drug having high binding affinity for the same protein for which the first drug has binding affinity, is administered simultaneously or before administration of the first drug, competitive displacement takes place at the binding site so that the first drug may be released in a higher concentration. The Examiner further cited to various sections of *Kawai, et al.* that allegedly teach the limitations of the dependent Claims.

The Examiner concluded that each and every element of Claims 1 and 5 are taught by *Kawai, et al.*

For the following reasons, the rejection is overcome.

Applicants have canceled Claims 1 and 5 and added new Claim 22. *Kawai, et al.* do not teach the last step of Claim 22, which is determining the ratio of the first free first drug ratio to the second free first drug ratio to give a change ratio. *Kawai, et al.* also do not teach that

determining this ratio thereby allows determination of whether the first drug binds to the plasma protein at the same site as any of the second or more drugs for which the binding site is known.

With respect to *Prichard et al.*, the Examiner asserted that *Prichard et al.* teach in vitro tests to investigate the plasma protein binding of bepridil using radiolabeled bepridil. The Examiner further asserted that *Prichard et al.* teach the general procedure they employed to determine the effects of other drugs on the in vitro plasma protein binding of depridil.

Prichard et al. do not teach the last step of Claim 22.

In view of the above remarks and newly presented Claim 22, the Examiner is requested to reconsider and remove this rejection.

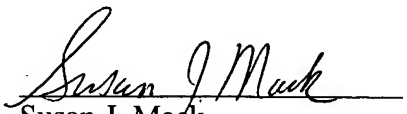
2. The elected Claims were rejected under 35 U.S.C. § 102(e) as being anticipated by *Kawai, et al.*(US Patent 7,029,653).

Kawai, et al., '653 do not teach the last step of Claim 22. Accordingly, the Examiner is requested to reconsider and remove this rejection.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Susan J. Mack
Registration No. 30,951

Date: July 31, 2006